Endoscope with disposable cartridge for the invagination of endoscope tube

This is the continuation of application PCT/LV98/00006 based on the priority applications P-97-190 from 03.10.97 (LV) and P-98-188 from 23.09.98 (LV).

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to the field of medicine, namely to colonoscopy and enteroscopy, but can also be used for industrial endoscopes.

2. Description of Background Art

The common feature of the endoscope, proposed in present application and of endoscopes according to known patents is a tube, eversible under fluid pressure. The inflated and everted tube invaginates an endoscope tube into explored channel and therefore was named by me as invaginator. The exploitation of invaginator is effective in case when it everts close to the objective and does not cover the latter.

The fluid pressure causes not only inflation and evertion of invaginator, but also its tight engagement with the endoscope tube. As a result of this engagement an everted part of invaginator becomes twice shorter that the endoscope tube.

U.S. Pat. 4, 321,915 to Leighton et al., U.S. Pat. 4,615,331 to Kramann and U.S. Pat. 5,259,364 to Bob et al., whose disclosures are incorporated herein by references, illustrate the attempts to overcome the effect of invaginator's engagement with an endoscope tube.

Invaginator according to the US Pat. 4,321,915 is mono-layered. To remove the double lag of invaginator there is suggested by the periodical change of pressure and vacuum and by extracting of endoscope tube till the moment when its objective coincides with the place of invaginator's evertion. But the investigated channel is tortuous and invaginator is a thin-walled tube. As a result together with the endoscope tube will be extracted also the invaginator. It seems to be complicated also the coincidence of objective together with the place of invaginator's evertion.

In the device according to US Pat. 4,615,331 invaginator is placed on the endoscope tube by long overlying parallel layers. In this connection the place of invaginator's evertion periodically moves away from the objective. The more important defect of multi-layered invaginator is

inconsequent unreeling of its layers. The premature evertion of lower layer will exclude or complicate evertion of others.

In the device according to US Pat. 5,259,364 the end of uneverted part of invaginator is attached to a chamber, which is an extra-organ storage of the supply portion of invaginator. The problem of engagement of the uneverted part of invaginator with the endoscope tube authors of US Pat. 5,259,364 propose to solve by feeding of working pressure into the uneverted part of invaginator. The working fluid pressure according to data of Gründl, Bob and Bob is varying from 0,4 till 1,2 bar (see US Pat. 5,686,968), but the uneverted part of invaginator, in spite of declaratory authors' assurance, inevitably communicates with the intestinal cavity. It is known that bursting of intestine starts at pressure of 0,17 bar and it bursts under the pressure of 0,235 bar (see www.anastomos.narod.ru/ourresult.htm). In addition to safety problem the US Pat. 5,259,364 does not solve the problem of displacement of invaginator's uneverted part from chamber to objective.

Thus, all known endoscopes with invaginator are insufficiently effective or dangerous.

The endoscope tube together with invaginator repeat all curves of explored channel. But bending of tube distal end is possible only till the definite number of curves. This is the second drawback of existing colonoscopes. Tube's end is bent by rotating of two rollers each connected to its pair of traction lines. Springs, comprising traction lines, on the distal end are continued by channels in the wall of cardan-jointed rings. Ends of traction lines are soldered to the distal ring of the cardan executive mechanism for bending the tube distal end. Outward extraction of traction line from the spring decreases gaps between cardan rings thus forming a small radius of a curve. At that the distal cardan ring pulls the opposite traction line in distal direction, thus ensuring an increase of space between rings. Difference of lengths of big and small half-circumferences of tube's curve is a product of «π» and diameter of an endoscope tube. Japanese authors point out that when 3-4 loops are formed, the distal end of an endoscope is was blocked, but biopsy forceps continued to function. This difference is explained by L. Aler formula

$$\frac{Q_1}{Q_2} = e^{\alpha \cdot f}$$

where: «Q_1» - manual power realizing traction lines extraction; «Q_2» - remaining from «Q_1» power, attached to a distal cardan ring or cutters of biopsy forceps; «e» - basis of natural logarithm; «α» - traction line rotations in radians; «f» - friction index between a traction line and a spring. Under fixed values «Q_1» and «f», value «Q_2» depends on value «α», but for two

consecutively connected traction lines of an endoscope the latter is twice as large as for one line of biopsy forceps.

The third drawback of known endoscopes is the problem of its maintenance. For recurrent use an endoscope tube is washed, disinfected and sterilized. However, there are reported cases of infecting patients with AIDS and other infections after endoscopy.

It has been practically proved that if an endoscope tube has more than 3-4 loops, it is impossible to introduce biopsy forceps into it and to take bioptate. This is the fourth drawback of the prototype.

SUMMARY OF THE INVENTION

The invention mainly pertains to the field of medicine and particularly is intended for the early diagnostics of colon cancer.

The objectives of the invention have been following: - ensure reliability, and easiness of introduction of endoscope tube into colon or others long flexuous channels; - ensure bending of the distal end of endoscope tube in flexuous channels; - make maintenance of an endoscope more convenient; - perform biopsy in flexuous channels. Implementation of these objectives will make colonoscopy available to any physician and make it easier for experienced endoscopists.

As the base for all variants of the construction of present invention serves an endoscope with invaginator, whose uneverted end is coupled with the distal part of endoscope tube, at that the invaginator is made by pleats and in compact state is held on said distal part.

In the simplest variant of present invention, the uneverted part of invaginator is enclosed into the everted one, and the end of the everted part is fixed on a seal of endoscope tube and connected to fluid pressure.

In preferred embodiments of present invention the invaginator is made in the form of hollow compact flexible cylinder which has a gap with a preservative of the distal part of endoscope tube. A compact hollow cylinder of the invaginator is formed of tightly compressed in longitudinal and transverse directions pleats of different forms of an eversible elastic tube placed at any angles with the longitudinal axis of an endoscope tube. For its flexibility the cylinder could have recurrent narrowings of an external diameter and widenings of its internal diameter.

Preferred embodiments of present invention comprise a disposable sterile cartridge for the invagination of endoscope tube, the cartridge could comprise: - a shell which has a projection at its proximal end, wherein could be enclosed: a preservative of the distal part of endoscope tube

which could be joined at the proximal end to a spring stop; a compressed spring; a spring distancer in which is located a distal seal of the endoscope tube coupled to an uneverted end of the invaginator; a fixator of compressed spring; an invaginator in the form of a hollow compact cylinder, which has a gap with preservative and could comprise a recurrent narrowings of an external diameter and widenings of its internal diameter, at that the everted end of invaginator is fastened on the distal end of said shell; - a proximal seal of the endoscope tube fastened on the distal end of said shell; - an anal dilator having a channel in its wall; - a tip of said endoscope tube, coupled with the distal end of said preservative, which one (the tip) has a protective glass, a channel for glass washing and blowing of intestine, an element for hermetic joining to the endoscope tube.

In preferred embodiments of present invention the cartridge for invagination of endoscope tube could be attached to a mechanism for its introduction. The mechanism for introduction could comprise a cylinder with two pistons, which are interconnected with distancers and segment of an elastic tube, but a cavity between them through a pedal cock communicates with fluid pressure, while a cavity between a proximal seal of the endoscope tube and a distal piston comprises a spring which returns pistons to their home position and through the pedal cock communicates with fluid pressure.

In preferred embodiments of present invention the inserted endoscope tube could comprise for coupling with cartridge: - an internal transverse pleats of its external cover, which raise tube's flexibility; - two air-ducts, where the larger one has a lateral opening into a cavity of the proximal seal of the disposable cartridge for invagination, but the smaller one - into a cavity of distal and proximal preservatives; - an areas for hermetic fixation of ends of preservatives; - a proximal preservative. At that a control block could be made as a desk unit, but the cock, which feeds the working pressure into the everted part of invaginator could be placed in pedal.

In preferred embodiments of present invention the system for bending of the distal end of endoscope tube in tortuous channels could comprise the sources of fluid pressure, connected to cavities of elastic tubes. The elastic tubes could comprise springs with traction lines, the tubes could be fixed to springs by thread, but the springs could be executed with pitch. The traction lines on distal end could be joined with springs, but in the control block - with manual extractors-intractors of traction lines, connected with elements ensuring synchronous fluid evacuation from the cavity of manually extracted traction line and fluid feeding into the cavity of introduced traction line. The distal end of tube and traction line could be finished by cylinder and piston or the tube could be finished by an elastic element, for example by sylphone, but a traction line could be connected with sylphone's distal end. A manual extractors-intractors of traction lines

could be made in the manner of a rod, but the sources of fluid pressure – in the manner of a piston and cylinder, positioned on the rod. An element ensuring synchronous fluid evacuation from the cavity of extracted traction line and fluid feeding into the cavity of introduced traction line could be made as a pinion mated with cogs of two rods. Each of two pinions is coupled only with its pair of traction lines, that is why bending of the tube's end could be performed in two stages. The cross-piece with a management lever, wherein central part is movably connected with the body of control block, but the ends are attached to four rods, could ensures simultaneous bending of the tube's end in any direction.

In preferred embodiments of present invention in order to conduct biopsy in torturous channels, the insertion and extraction of biopsy forceps could be realized with a help of fluid pressure which is connected through a cock to the cavity of the biopsy channel, the entrance to which is sealed by a seal of biopsy forceps, and at the distal end of which there is a piston of the biopsy channel. At that the biopsy forceps comprise a flexible hermetic tube, which is connected to source of fluid pressure, but the distal end of the tube and traction lines could be finished with a cylinder and a piston. The unit cylinder-piston is possible to replace with a segment of sylphon, the end of which is connected to traction line.

The subject of present invention is an endoscope, comprising

- an invaginator whose uneverted end is coupled with the distal part of the endoscope tube, at that said invaginator is held on said distal part of the endoscope tube;
- an invaginator formed of pleats, tightly compressed in longitudinal and transverse directions in a compact hollow cylinder, which has a gap with said distal part of the endoscope tube.

The subject of present invention also is an endoscope with a disposable cartridge for the invagination of endoscope tube, the cartridge comprises: invaginator whose uneverted end is coupled with the distal part of the endoscope tube, said invaginator is formed of pleats, tightly compressed in longitudinal and transverse directions in a compact hollow cylinder, which has a gap with said distal part of the endoscope tube and is held on said distal part.

Both foregoing subjects of invention could also comprise:

- o said cylinder of invaginator having narrowings of external diameter and widenings of internal diameter,
- o a shell for conducting the distal part of endoscope tube with invaginator along rectum, at that the diameter of said shell is commensurate to the diameter of said invaginator,
- o sliding seals of endoscope tube, isolating a cavity of the everted part of invaginator,
- o an anal dilator,

- o said anal dilator with a channel in its wall,
- o a spring of invaginator,
- o a preservative of the distal part of endoscope tube united with tube's tip, at that the proximal end of preservative and the tip have areas for hermetic fixation to the distal part of said endoscope tube,
- o said tip comprises a protective glass and communicates with intestinal cavity,
- o a mechanism for introduction of the endoscope tube which is a cylinder-piston unit having a hermetic cavity, confined by a cylinder, a piston and a segment of an elastic tube connected to fluid pressure,
- o an endoscope tube with an transverse pleats of its external cover, which are directed internally,
- o an endoscope tube with distal drives of traction lines bending its distal end, which are springs executed with pitch and enclosed inside elastic tubes connected to fluid pressure,
- o an endoscope tube with distal drives of traction lines bending its distal end, which are cylinder-piston units connected to fluid pressure,
- o an endoscope tube with distal drives of traction lines bending its distal end, which are sylphones connected to fluid pressure,
- o an endoscope tube with a biopsy channel connected to fluid pressure and a biopsy forceps which are flexible hermetic tube with a biopsy channel's piston on tube's distal end,
- o said biopsy forceps having a distal drive of forceps which is a cylinder-piston unit connected to fluid pressure,
- o said distal drive of forceps which is a sylphone connected to fluid pressure.

The subject of invention also is a method of prophylaxis from getting infected of endoscope tube and patient, the method comprises:

- o hermetic connection of endoscope tube to tube's distal part preservative an to a tip united with said preservative, having a protective glass and communication with intestinal cavity,
- o hermetic connection of said preservative to the uneverted end of invaginator of endoscope tube, which is an elastic tube everted under fluid pressure, the elastic tube is formed by pleats in a compact hollow cylinder which has a gap with said preservative,
- o feeding of fluid pressure through a channel in endoscope tube under the protective glass of said tip.

of tube 3 becomes bared. It could happen both due to absence of gap between tube 3 and uneverted part of invaginator and to a friable structure of said uneverted part, which under the action of air pressure engages to tube 3.

The problem of engagement of the uneverted part of invaginator with the endoscope tube 3 was solved by invaginator formed of pleats tightly compressed in longitudinal and transverse directions in a compact hollow cylinder 23 (see FIG. 2), the cylinder has a gap 25 with the distal part of an endoscope tube 3 and for its flexibility could have a recurrent narrowings of external diameter and widenings of its internal diameter respectively.

Further follows more complicated variants of present invention (see FIG. 2, FIG. 3, FIG. 4) comprising an endoscope tube 3 with control block 2 and communication branch. There are possible, for example, a following constructions. Air-duct 15 and cock 17 positioned on control block 2 or in pedal, connect source of fluid working pressure with opening 21 into the cavity of seal 13, which communicates with cavity 14 of shell 22. The distal part of shell 22 is commensurable in relation to length and diameter to uneverted part of invaginator 23, but the proximal part – to the compressed spring 10. Everted end 12 of invaginator 23 is connected to shell 22 by ring 16. Invaginator 23 has narrowings and widenings 24, as well as gap 25 with distal preservative 26, at that the gap 25 is keeping also at working pressure in the cavity 14. Ends of distal 26 and proximal 27 preservatives and corresponding to them places of tube 3 have areas 28 for interconnection and hermetization. Seal 29 on end 7 of invaginator 23 separates cavity 14 from cavity 25, which communicates with the intestinal cavity. A distancer 30 prevents deformation of seal 29 by spring 10. Ends of compressed spring 10 are based on distancer 30 and stop 11 at the end 28 of preservative 26. Stop 11, in its turn, is positioned on the projection 31 of shell 22. The distal end of preservative 26 ends with tip 6 with channels 32 for washing of protective glass 33 and blowing-up of intestines, as well as an element for connection to endoscope tube 3. On the border of narrow and broad parts of shell 22 there is an area of intermediate diameter with indented elastic ring 34 for fixation of compressed spring 10. Channel 35 of anal dilator 19 is used for decompression of intestines during intubation. In the tube 3, besides the enumerated, there are elastic tubes 36, 37 comprising springs 38, 39 and traction lines 40, 41. Tubes 36, 37 are connected to springs 38, 39 with thread 42. Near mechanism 43 for bending the distal end of tube 3, ends of tubes 36, 37 are closed with plugs 44, which also connect springs 38, 39 with traction lines 40, 41. Proximal ends of tubes 36, 37 are connected with sources 45 of fluid pressure. Proximal ends of traction lines 40, 41 are connected with their manual extractors-intractors 46, but the latter - with element 47 which ensures synchronous evacuation of fluid from the cavity of the extracted traction line 40 and feeding of fluid into the cavity of the introduced traction line 41.

Endoscope tube 3 has an internal pleats 48 of its external cover, air-duct 49 with two openings 50 designed for vacuum fixation of preservatives 26, 27 to tube 3 and also has a removable

sleeve gasket 51. Control block 2 has a cock 52 of an air-duct 49. Seal 13 is hermetically connected to a mechanism 53 for introduction of endoscope tube 3. A mechanism 53 for introduction of tube 3 is operated by pedal 54 but lever 55 realizes bending of tubes end. Cylinder 56, two pistons 57, distancers 58 and segment of an elastic tube 59 confine a cavity 60, which is connected with source of fluid pressure by means of cock in pedal 54. Cavity 61 comprises return spring 62 and is connected with source of fluid pressure by means of cock in pedal 54. Seal 64 and nut 65 are mounted on biopsy forceps 63, but piston 66 is positioned at their distal end. Seat for seal 64 and nut 65 is located at entry 67 to biopsy channel, which is positioned with cock 68 on control block 2. Sylphon 69, which serves as a source of fluid pressure in the intensifier of traction line of biopsy forceps 63, could be combined with its handle.

Marks made on preservative 27 and tube 3 serves for their correct positioning. Then mechanism 53 is mounted on tube 3 and cartridge for invagination is fixed. Pressing of cock 52 will ensure vacuum fixation of preservatives 26, 27 to tube 3. After introduction of seal 13 into cylinder 56 endoscope preparation for work is completed.

After the patient has been placed on an endoscope table, a cartridge is oiled and introduced into the rectum and its ampoule is examined as if with a rigid rectoscope. The fluid pressure in cavity 14 is fed by pressing the cock 17 thus releasing the distancer 30 from coupling with fixator 34 and shell 22. Thereby spring 10 is released and it is possible to proceed with invagination of tube 3. Eversion of invaginator 23 and introduction of tube 3 into the colon occurs under fluid working pressure in cavity 14 at the moments of pressing pedal 54. During the endoscopy procedure intestines are to be distended. Gas into intestines is constantly supplied through gas/liquid channel of tube 3 and through channel 32 of tip 6 thus preventing penetrating of intestinal content under a protective glass 33. Gas evacuation from intestines occurs through a channel 35 of anal dilator 19.

Bending of mechanism 43 is realized by means of fluid pressure sources 45, manual extractors-intractors 46 of traction lines 40, 41 and by means of elements 47 which ensure evacuation of fluid from the tube 36 which comprises extracted traction line 40, and feeding of fluid in the cavity of tube 37 containing introduced traction line 41. As a result of fluid evacuation the elastic tube 36 and spring 38 are shortened. Considering, that their distal end is connected with traction line 40, this shortening relieves its manual extraction. Fluid pressure in tube 37 the latter and spring 39 elongates towards executive mechanism 43 thus relieving manual intraction of traction line 41. Thread 42 twisted on tubes 36, 37, connects them with springs 38, 39. Thus, evacuation and feeding of fluid ensure application of powers to distal ends of traction lines 40 and 41;

manual extraction and intraction of traction lines 40, 41 creates synchronous efforts on their proximal ends. Mechanism 43 of tube 3 is bent downwards by the above-mentioned method. During bending of mechanism 43 upwards, all above enumerated elements are moved in opposite directions, but bending of mechanism 43 to the left and to the right is implemented by the second pair of traction lines, which work similarly. In intermediate positions mechanism 43 is bent by interchangeable application of both pairs of traction lines. Element 47 made in the shape of a crosspiece with lever 55 ensures simultaneous bending of mechanism 43 in any direction.

As during colonoscopy tube 3 repeats all natural flexures of the colon its extubation must not be accelerated. Anal dilator 19 through which extubation is to be conducted eliminates unpleasant sensations caused by this process.

The most practically important version of the invention is a colonoscope with endoscope tube 3 without biopsy channel. A disposable cartridge ensures an available to all and atraumatic transportation of tube 3 in the colon, preservatives 26, 27 protect a patient from infections seated in endoscope tube 3, but a tube 3 - from getting contagious during endoscopy. The management ergonomics of such colonoscope also makes it available to any physician: during endoscopy a physician in sedentary position, watches the screen, presses pedal cock 17 with one foot, pedal 54 with another, the right hand controls lever 55, but in case of necessity washes the protective glass 33 by pressing on the cock with the left hand. Such colonoscope is necessary firstly for family doctors, gastroenterologists and surgeons for regular screening of colon cancer. Having selected "suspicious" patients out-patient physicians will direct them to an in-patient clinic for conducting biopsy and other thorough examination.

For realization of biopsy a cartridge with tip 6, without glass 33 is used. Having exhausted the possibility of manual insertion of forceps 63, it is necessary by means of seal 64 and nut 65 to hermetically seal entry 67 into the biopsy channel and connect it by means of cock 68 to the source of fluid pressure. Further insertion of forceps 63 is performed by their manual intraction and due to fluid pressure on piston 66, but extraction – by switching cock 68 in the position "vacuum" and manual extraction of forceps 63. Due to location of source 69 of fluid pressure of traction line intensifier in the handle of forceps, taking of bioptate is made as previously - approach of rings ensures movement of the traction line inwards, but detachment - extraction of the traction line.

Specifications of graphic materials' marks on FIG.1-5:

2 - control block with communication branch;

3 – endoscope tube;

4 - everted part of invaginator (on FIG. 5 only);

5 - source of working pressure in cavity 14 (on FIG. 5 only);

6 - tip of endoscope tube 3;

7 - uneverted end of invaginator 23;

8,9 – rings at the end 7 of invaginator (on FIG. 5 only);

10 - compressed spring;

11 - stop for spring 10;

12 - everted end of invaginator 23;

13 – proximal seal of tube 3;

14 - cavity of everted part 4 of invaginator 23;

15 – air-duct for feeding fluid working pressure into cavity 14;

16 - ring, fixing end 12 of invaginator 23;

17- cock of air-duct 15;

18 – manometer (on FIG. 5 only);

19 - anal dilator;

20 – rectum (on FIG. 5 only);

21 – air-duct 15 opening on tube 3;

22 - shell of cartridge for invagination;

23 - invaginator formed in a compact flexible cylinder;

24 - narrowings and widenings of cylinder of invaginator 23;

25 - gap (cavity) between cylinder of invaginator 23 and preservative 26;

26 - distal preservative of tube 3;

27 - proximal preservative of tube 3;

28 - areas on tube 3 and at the ends of preservatives 26, 27 for their hermetic connection;

29 – distal seal between tube 3 and end 7 of invaginator 23;

30 - distancer between spring 10 and invaginator 23 comprising seal 29;

31 - projection on shell 22 for stop 11;

32 - channel in tip 6;

33 - protective glass of tip 6;

34 - elastic ring, fixing spring 10 in compressed state;

35 - channel in anal dilator 19;

36 - lower elastic tube of extractor-intractor of traction lines;

37 - upper elastic tube of extractor-intractor of traction lines;

38 - lower spring of extractor-intractor of traction lines;

39 - upper spring of extractor-intractor of traction lines;

40 – lower traction line of extractor-intractor of traction lines;

41 – upper traction line of extractor-intractor of traction lines;

42 - thread fixing elastic tubes 36, 37 to springs 38, 39;

43 – mechanism for bending of distal end of tube 3;

44 - plug closing tubes 36, 37 and connecting springs 38, 39 with traction lines 40, 41;

45 - sources of fluid pressure;

46 - manual extractors-intractors of traction lines 40, 41;

47 – element for extraction-intraction of one or two pairs of traction lines;

48 - pleats of external cover of tube 3;

49 – air-duct into cavity of preservatives 26, 27;

50 - distal and proximal openings of air-duct 49 on tube 3;

51 - sleeve gasket;

52 – air-duct 49 cock on control block 2;

53 – mechanism for insertion of endoscope tube 3;

54 – pedal for switching on mechanism 53;

55 - lever of element 47, made in a shape of cross-piece;

56 - cylinder of mechanism 53;

57- pistons of cylinder 56;

58 – distancers between pistons 57;

59 – segment of elastic tube, attached to pistons 57;

60 - hermetic cavity, enclosed by segment of elastic tube 59 and pistons 57;

61 - hermetic cavity, enclosed by seal 13 and distal piston 57;

62 - spring returning pistons 57 to home position;

63 - biopsy forceps;

64 - seal of entry 67 into biopsy channel;

65 - nut, fixing seal 64;

66 - piston of biopsy forceps;

67 - entry into biopsy channel;

68 - cock feeding the fluid pressure into biopsy channel;

69 - source of fluid pressure connected with cavity of biopsy forceps 63;

70 - cutters of biopsy forceps 63;

71 - distal intensifier (drive) of traction line of the cutters 70.